

REMARKS

Claims 1-6, 9-13, 32-39, 41-48, 62-73 are pending in this application. Claims 7, 8, 14-31, 40 and 49-61 have been canceled without prejudice and claims 69-73 are new.

Restriction Requirement

The Examiner has made a three-way restriction in the present application, restricting the claims as follows:

- I. Claims 1-23, 32-60 and 62-68, drawn to a catheter and method of using it;
- II. Claims 24-31, drawn to a catheter with a cam and a drive shaft; and
- III. Claim 61, drawn to a catheter kit.

In a telephone conversation with the Examiner on December 16, 2003, Applicant elected to prosecute Group I, claims 1-23, 32-60 and 62-68, without traverse. Applicant hereby affirms election of Group I.

The title of the invention has been changed to read --METHODS AND DEVICES FOR REMOVING MATERIAL FROM A BODY LUMEN-- Applicant appreciates the Examiner's suggestions with respect to the title, however, Applicant believes that the some claims are directed to broader aspects than a catheter which is deflectable or rotatable (see as-filed and currently amended claim 62 and new independently claim 69).

Claim Objections

Claims 21 and 53 were objected to for various informalities. Claims 21 and 53 have been canceled to obviate this rejection.

Claim Rejections under 35 U.S.C. §112

Claim 9 and 49 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 49 have been amended to address this objection.

Claim Rejections under 35 U.S.C. §102

Claims 1 and 2 were rejected as being anticipated by U.S. Patent No. 5,620,447 to Smith et al. ("Smith"). Claims 1-8, 10, 14-23, 49-60 and 62 were rejected as being anticipated by U.S. Patent No. 4,979,951 to Simpson ("Simpson"). Claims 39-41 and 44-48 were rejected as being anticipated by U.S. Patent No. 5,911,734 to Tsugita et al. ("Tsugita").

Claim Rejections under 35 U.S.C. §103(a)

Claims 11-12 and 59 were rejected as being obvious over Simpson in view of U.S. Patent No. 5,250,059 to Andreas et al. ("Andreas"). Claim 13 was rejected as being obvious over Simpson in view of U.S. Patent No. 5,569,277 to Evans et al. ("Evans").

Allowable Claims

The Examiner has indicated that claims 32-38 and 63-68 are allowed. Applicant appreciates the indication that claims 40, 42 and 43 would be allowable if rewritten into independent form. Claim 39 has been amended to include the limitations of dependent claim 40 thereby placing claims 39 and 41-48 in condition for allowance.

DISCUSSION

Amended independent claim 1 is allowable over Smith and Simpson since neither Smith nor Simpson disclose or suggest a catheter including "a rigid housing rotatably coupled to the distal end of the flexible body, the housing having a window; and a tissue debulking

assembly disposed at least partially within the rigid housing, the tissue debulking assembly being movable from a first position to a second position, the debulking assembly being positioned within the window in the first position and extending out of the window in the second position, the debulking assembly changing an angular orientation of the rigid housing relative to the flexible body when moving from the first position to the second position.” Nowhere do Smith and Simpson disclose or suggest deflecting the tip of the catheter when moving a debulking assembly from a first position within the window to a second position which is partially exposed out of the window.

Amended independent claim 62 is patentably distinguishable from Simpson since Simpson does not disclose or suggest “advancing the catheter to move the rotating cutter through occlusive material in the body lumen, the rotating cutter remaining in the exposed position so that the cutter and the window maintain their orientation with respect to one another when advancing the catheter through the occlusive material, the occlusive material cut by the rotating cutter being directed through the cutting window and into the collection chamber as the catheter is advanced through the occlusive material.” For the purpose of illustration only, and without limiting the scope of the claims, a preferred embodiment is now described with reference to Figs. 17-20 of the present application. The debulking catheter 20 has rotating cutter 32 which can be moved to the exposed position of Fig. 19. When the catheter 20 is in the exposed position, the entire catheter is advanced through the body lumen to cut material. As the material is cut, the material is directed through the window 32 and into the collection chamber 53.

Simpson discloses a catheter having a cutting window which remains fixed at a location while the cutting element translates past the window to cut material. Thus, Simpson clearly does not disclose or suggest advancing the catheter to move the rotating cutter through the occlusive material let alone with “the rotating cutter remaining in the exposed position so that

the cutter and the window maintain their orientation with respect to one another when advancing the catheter through the occlusive material” as claimed.

Applicant submits that it would not have been obvious to modify Simpson to advance the catheter of Simpson through the body lumen when cutting material since such a modification is entirely inconsistent with the teaching in Simpson. Simpson holds the catheter at a fixed location when cutting tissue rather than advancing the catheter through the body lumen as claimed. To this end, Simpson provides a balloon which is inflated to fix the location of the catheter and force tissue into the window.

New independent claim 69 is allowable over the cited art for similar reasons that amended independent claim 62 distinguishes, namely, that the cited art does not disclose or suggest the steps of “providing a debulking catheter having a body, an opening leading to a collection chamber, and a cutter, the cutter being movable between a stored position and an exposed position, the cutter becoming at least partially exposed when moving from the stored position to the exposed position” and “advancing the debulking catheter after the exposing step and during the rotating step, wherein the rotating cutter and the opening advance together so that material cut by the rotating cutter is directed through the opening and into the collection chamber as the catheter is advanced.” New claim 69 distinguishes over Simpson since Simpson does not disclose or suggest advancing the catheter let alone advancing “the rotating cutter and opening together” as claimed. Simpson is directed to a catheter having a window which remains fixed during cutting rather than being advanced in the claimed manner.

Dependent claims 70-73 are allowable since they depend from allowable independent claim 69 and because they recite independently patentable features.

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CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration of the pending claims. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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By: Craig P. Wong
Craig P. Wong
Reg. No. 45,231

TOWNSEND and TOWNSEND and CREW, LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111
Telephone: (206) 467-9600
Telefax: (415) 576-0300

CPW/acg